4/15/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
d1846b

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

May 27, 1998

James E. Rich
President
Animal Dermatology Laboratories
16782-B Hale Avenue
Irvine, CA 92606

WL-32-8

Dear Mr. Rich:

During an inspection of your veterinary drug manufacturing facility located at Irvine, California, conducted on April 6 through April 8, 1998, our investigator found significant deviations from the Current Good Manufacturing Practice for Finished Pharmaceuticals regulations (Title 21, Code of Federal Regulations, Part 211). Such deviations cause veterinary drugs manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found overall failure to validate the production process, as well as: 1) failure to conduct any testing of incoming components, or to conduct appropriate validation of the supplier's test results; 2) failure to establish written procedures for in-process testing or finished product testing; 3) failure to maintain adequate batch records in that they fail to document information such as: actual amounts of added ingredients, actual yield, theoretical yield, type, size and number of bottles filled, fill weight verification of the finished product containers, and labeling control records with copies of labels; and 4) failure to assess the stability of drug products for the purpose of determining appropriate storage conditions and expiration dates.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of veterinary drugs, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to:

Mary M. LoVetere
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612-2445

Sincerely,

Elaine C. Messa
District Director

cc: State Department of Health Services
Food and Drug Branch
Stuart E. Richardson, Jr., Chief
714 "P" street, Room 400
Sacramento, CA 95814